

Remarks

Amendment to the claims

Claim 15 is amended to better define the structure of the instrument, in view of the remarks hereinbelow, as requested by the Examiner in the Advisory Action. In particular, claim 15 now specifies that the instrument comprises “at least 1 light source emitting light toward a reaction vessel containing fluorescent compounds, a plurality of a least 5 optical fiber bundles, each said bundle receiving homogeneously distributed light emitted from the reaction vessel, and transmitting said light to one of a plurality of at least 5 separate fluorescent detector entities”. Support for this amendment is found lines 14-18 on page 17 of the application as originally filed. Consequently, no new matter has been added by this amendment, entry is respectfully requested. With entry of the instant amendment claims 15-17 are pending and under consideration.

Claim rejections under 35 U.S.C. §103

Claims 15-17 were rejected under §103(a) as being unpatentable over Bell and Ranford-Cartwright (2002) Trends in Parasitology, v.18(8), pp. 337-342, as evidenced by Wittwer et al. (1997) Biotechniques, v.22(1) pp. 176-181, in view of Hiratsuka et al. (2002) Clin. Biochem., v.35(1), pp. 35-40, Epstein et al. (2002) Anal. Chim. Acta, v.469, pp. 3-36 and Glazer et al., U.S. Patent No. 6,150,107 and Pinkel, U.S. Patent No. 5,837,196. Pinkel was cited for the first time in the Final Office Action in response to the latest amendments to the claims. The rejection is obviated by the amendments entered.

Claim 15 was rejected over a hypothetical combination of Wittwer and Pinkel. Further, on pages 7-9, it is alleged that it would have been prima facie obvious to combine the teachings of Pinkel with those of Bell as evidenced by Wittwer and with the motivation provided by Epstein and also general guidance provided by Glazer. (Hiratsuka is not mentioned in the body of the rejection.) Although it is not stated expressly in the final Office Action, it appears that the rejections on pages 7-9 apply to all claims.

*Prior art lacks a critical limitation on distinct wavelength windows*

Without admitting whether there would have been a motivation to combine the references as alleged, the Applicants respectfully point out that the hypothetical combination of Wittwer and Pinkel (or Wittwer, Pinkel, Epstein and Glazer) falls short of the present invention. As is explained in detail below, the hypothetical combination would lack a claim limitation “at least 5 separate fluorescent detector entities, each of said detector entities having a central detection wavelength, *said wavelengths being distinct from each other by at least 25 nm*”.

With respect to the detector entities, it is alleged that Wittwer teaches the use of three different filters, for the detection of SYBR Green I, rhodamine and Cy5, which would meet the limitation of having detection central wavelength separated by at least 25 nm. It is noted however, that Wittwer does not teach “at least five” such separate detector entities.

Pinkel is introduced to fill the gap with respect to “at least five” detector entities. Pinkel allegedly teaches a plurality of fiber bundles, each transmitting the signal to a detector entity. The examiner alleges that Pinkel teaches “at least five” detector entities. Assuming for the sake of argument, that Pinkel teaches a plurality (at least five) of separate detector entities, there is nothing in Pinkel to suggest that these detectors have “a central detection wavelength, *said wavelengths being distinct from each other by at least 25 nm.*” Nowhere in the reference is it suggested that the detectors within the same device have different detection windows or are different in any way. The limitation “at least five...detection wavelengths” is also absent from the remaining references (Epstein and Glazer). At the same time, the examiner expressly admits that the wavelength window is a critical structural limitation for a detector: “All it matters is the *emission wavelength window* for which each of the fiber optic detectors is configured to detect.” (Final Office Action, p. 7, lines 1-2, emphasis added). Yet it is exactly this limitation that is entirely absent from the prior art.

For an invention to be obvious, *all the claim limitations* must be taught or suggested by the prior art. See MPEP 2143.03. Because a critical limitation of claim 15 is neither taught nor suggested by the prior art, the claim is not obvious over the combination of cited references. For this reason, withdrawal of the §103 rejection is respectfully requested.

*The missing limitation may not be added to the prior art*

As a separate ground for traverse, the applicants note, that segregation of the wavelengths is contrary to the principle of operation of the Pinkel device. The Pinkel device uses a plurality of reaction vessels (fibers). The number of fibers is 1,000 to 3,000 (col. 8, line 40), organized into a series of bundles (e.g. 12 bundles, Fig. 4). The signals from the bundles do not mix together and thus do not need to be segregated by the detector. Pinkel states: “Each detector is subsequently *known to be associated with a particular biological binding partner* and there is *no need* to preserve a fixed spatial relationship between any of the transmission ends.” (Col. 13, lines 2-5). In other words, there are multiple vessels, each emitting a single wavelength. In such a configuration, there is no need for detectors to parse out several wavelengths. In contrast, in the present invention, there is a single vessel containing multiple fluorescent compounds, irradiated by a light source. The fluorescent compounds emit multiple wavelengths altogether at the same

time. Claim 1 as amended recites that the resulting light is homogeneously transmitted to multiple detectors via at least 5 fiber bundles. In other words, each fiber bundle transmits the same light to multiple detectors where the wavelengths composing said light need to be parsed out (See p. 18, lines 9-17, describing one-tube multiplex PCR, and Fig. 4 showing the unit detections with filters and specific wavelength detections). The amendment clearly distinguishes the Applicants' device from the Pinkel device. The principle of operation of the Pinkel device is an exact opposite of the applicants' principle. These principles are mutually exclusive.

MPEP 2143.01(V) states that "If the proposed modification or combination of the prior art *would change the principle of operation* of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)." Because the proposed modification of the Pinkel device would change its principle of operation, the Pinkel reference may not render the claim obvious. For this reason, withdrawal of the §103 rejection is respectfully requested.

For the reasons set forth above, reconsideration and withdrawal of the obviousness rejection of claim 15 are respectfully requested.

Claims 16 and 17 depend upon claim 15 and therefore incorporate each and every limitation of that claim. For the reasons set forth with respect to claim 15, withdrawal of the rejections of the dependent claims 16 and 17 is also respectfully requested.

Conclusion:

In view of the above, Applicants believe that all claims now pending in this application are in condition for allowance. Applicants respectfully request a 1-month extension of time to respond to the Final Office Action mailed April 29, 2008. The commissioner is hereby authorized to charge the fee due under 37 CFR § 1.17(a)(1), to Deposit account No. 50-0812.

It is believed that no other fees are due at this time. However, the Commissioner is authorized to charge any fee deficiency or credit any overpayment to Deposit Account No. 50-0812.

If the Examiner believes that a telephone conference would expedite prosecution of this application, please call the undersigned at the number below.

Respectfully submitted,



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